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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94502-7070
Telephone: (510) 337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference No.: 2953482

October 21, 1997

Mark E. Curry
Virxcan Products
941 W. Moana Ln., #127
Reno, NV 89509

WARNING LETTER

Dear Mr. Curry:

This letter is in reference to your firm's marketing and distribution of the products "Virxcan Tablets", "Virxcan Sunskin Salve", "Body Tone Tablets", and "Essiac Extract." The labeling for these products make claims for the cure, treatment, or mitigation of diseases.

Claims for "Virxcan Tablets" and "Virxcan Sunskin Salve" include, for example, "treating internal malignancies in the liver, kidneys, colon, prostate, female sex organs, breasts, lung, and throat areas..."; "alleviating candidiasis infection"; treatment of gum disease; "inhibiting carcinogenic growth"; "virus related disorders"; "internal growths"; treating "medically diagnosed malignancies in both breasts, an ovarian cyst, and a fibroid tumor." In addition, your directions include "Oral ingestion of one (1) Virxcan tablet ... should produce results in the direction of non-activity of malignant growth. Large growths with lengthy history may take much longer."

Claims for the product "Body Tone" include, for example, treating "multiple sclerosis, muscular dystrophy, and Parkinson's disease."

Claims made for the product "Essiac Extract" include, for example, "Prevents build-up of excess fatty deposits in artery walls, heart, kidney tubules and liver; Halts diarrhea and checks internal hemorrhaging...; Counteracts detrimental effects of aluminum, lead, and mercury poisoning; Reduces, perhaps eliminates heavy metal deposits in the tissues, especially those surrounding the joints, to relieve inflammation and stiffness."

In addition, your product "Virxcan Sunskin Salve" is subject to the OTC Final Rule for "Wart Remover Drug Products" [21 Code of Federal Regulations (CFR), Sections 358.101 through 358.150] since your labeling claims the product is effective for wart removal.

We consider your promotional brochure to be labeling which makes therapeutic claims for these products.

These claims cause the products to be drugs as defined in [Section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act)].

The products are also "new drugs" [Section 201(p) of the Act] since they have not been shown to be safe and effective. Therefore, they may not be marketed in the United States without approved new drug applications [Section 505].

These drugs are also misbranded [Section 502(f)(1) of the Act] because the labeling fails to bear adequate directions for use and because the labeling is false and misleading, as it suggests that the products are safe and effective for their intended uses when this has not been established [Section 502(a) of the Act].

This letter is not intended to be an all inclusive review of all labeling and products marketed by your firm. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations. You should also include an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, please state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be sent to Marie K. Kinkade, Drug/Bioresearch Monitoring Team Leader; Food and Drug Administration; 1431 Harbor Bay Parkway; Alameda, CA 94502 (phone 510-337-6823).

Sincerely,

Charles D. Moss

Charles D. Moss
Acting District Director
San Francisco District